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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|--------------------------|----------------------------|------------------|
| 09/830,986 | 05/03/2001 | Andreas Bernkop-Schnurch | 030560-056 | 7285 |
| 21839 | 7590 | 12/14/2006 | EXAMINER | |
| BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404 | | | RAMACHANDRAN, UMAMAHESWARI | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 09/830,986 | Applicant(s) BERNKOP-SCHNURCH, ANDREAS | |
| | Examiner Umamaheswari Ramachandran | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,28,29,31-33,35-38 and 110 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,28,29,31-33,35-38 and 110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the remarks submitted on Sep 18 2006 amending claim 1. Claims 2-27, 30, 34, 74, 109 are canceled. Claims 39-73, 75-108 are withdrawn. Claims 1, 31 and 32 have been amended. Claims 1, 28, 29, 31-33, 35-38, 110 are pending in the application and are being examined on the merits herein.

Applicant's arguments against 35 U.S.C 112 (2) rejection of claim 31 is found to be persuasive and the rejection is withdrawn. Applicant's arguments against 35 U.S.C 102 (b) rejection of claims 1, 33, 35-38 anticipated by Omura et al. (U.S. 5,064,495) is found to be persuasive after the amendment of claim 1 and the rejection is withdrawn. Applicant's arguments against 35 U.S.C 102 (b) rejection of claims 1, 33, 35-38 anticipated by Constancis et al (U.S. 5,646,239) is found to be persuasive after the amendment of claim 1 and the rejection is withdrawn. Applicant's arguments against 35 U.S.C 102 (e) rejection of claims 1, 33, 35-38 anticipated by Marchant et al. (U.S. 6,514,535) is found to be persuasive after the amendment of claim 1 and the rejection is withdrawn. Applicant's arguments against 35 U.S.C 103 (a) rejection of claims 28-29 by Marchant et al. (U.S. 6,514,535) and Constancis et al (U.S. 5,646,239) is found to be persuasive and the rejection is withdrawn.

Applicant's arguments against the priority of the claims in the instant application for a priority date of November 4 1998 is not persuasive. The specification of the priority document (certified copy of the foreign priority document, Australian Application No. 1828/98) does not provide support of the said thiolated polymers of claim1: thiolated copolymer of acrylic acid and divinyl glycol, a thiolated polymer of chitosan, a thiolated

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polymer of sodium carboxymethylcellulose, a thiolated polymer of sodium alginate, a thiolated polymer of sodium hydroxypropylcellulose, a thiolated polymer of hyaluronic acid, a thiolated polymer of pectin, and derivatives of said thiolated polymers. Hence the applicant is granted priority only to Nov 4 1999 as the filing date for the application. The following new rejection has been made, based on the priority date of the application being Nov 4 1999.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 28, 29, 31- 33, 35-38 and 110 are rejected under 35 U.S.C. 102(a) as being anticipated by Bernkop-Schnurch et al (Pharmaceutical Research, Vol. 16, No. 6, 1999).

Bernkop-Schnurch et al teaches the improvement of mucoadhesive properties of polymer polycarbophil (copolymer of acrylic acid and divinyl glycol) by thiolating them with sulfhydryl groups (abstract, p 880, Table 2, col. 2, para 3, conclusions, lines 1-3). The reference teaches the adhesive properties of polycarbophil-cysteine conjugates were evaluated in vitro on excised porcine intestinal mucosa by determining the total work of adhesion. The reference further teaches the values of TWA of polymer-cysteine conjugate 16:1 to be $191 \pm 47 \mu\text{J}$ and $280 \pm 67 \mu\text{J}$ for the polymer-cysteine conjugate 2:1 at pH 6.8 (p 879, Fig. 4). This addresses claim 1, 35 and 110. The reference teaches polycarbophil-cysteine conjugates with thiol group concentrations (Table 1, p 877) ranging from 0.3-142 μMole per gram polymer. This addresses claims 28 and 29. The reference teaches that cysteine is covalently bound to the polymer by the formation

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of amide bonds (p 876, para 3, synthesis of polymer-cysteine conjugates). This addresses claims 31 and 32. The reference teaches that the polymer has at least one free thiol group as demonstrated by the mucin binding studies (p 879, para 2). This addresses claim 33. The reference further teaches the increase in TWA of the polycarbophil-cysteine conjugate 2:1 was determined to be 2.69 fold compared to unmodified polycarbophil at pH 6.8 (p 880, lines 1-3) thus addressing claims 36-38.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER